Remarks

After careful consideration of the outstanding Office Action, this application has been amended accordingly, and favorable reconsideration and allowance of the claims of record is herewith respectfully requested.

Claims 1 through 8 were previously cancelled; claims 9 through 29 are pending in the application; and claim 9 is the only claim amended in this amendment.

At page 3, paragraphs 5 through 8 of the outstanding Office Action, the Examiner rejected claims 9 through 29 under 35 U.S.C. 112, second paragraph, as being indefinite, and both pointed out the indefiniteness and proposed corrections thereto. The undersigned has followed the suggestions of the Examiner and claim 9 has been rewritten to avoid the lack of antecedent basis specified in paragraphs 6 through 8. Accordingly, the withdrawal of the latter rejection is believed to be in order and is respectfully requested.

At page 2, paragraph 3 of the Office Action, the Examiner rejected the claims of record "under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." More specifically, the rejection is based upon alleged lack of enablement because applicant allegedly has "failed to provide any formulas and/or algorithms that would enable the 'model computing means'."

The burden is, of course, upon applicant to prove by **convincing** evidence that the specification teaches one how to make and use claimed invention **without** undue experimentation. Whether the specification is

enabling involves consideration of (a) the nature of the invention, (b) the state of the prior art and (c) the level of skill in the art. No matter the determination of any one or all three of the latter factors, the specification need not disclose what is well known to those skilled in the art and preferably omits that which is well known to those skilled in the art and already available to the public. The latter is the position of the U.S. Patent and Trademark Office as is reflected in the Manual of Patent Examining Procedure at Sections 2164.05, 2164.05(b), etc.

First and foremost, the "model computing" means specifically emphasized by the Examiner is described at page 2 of the present specification, the second paragraph thereof. As the latter portion of the specification states, depending upon the current value of the present active substance concentration calculated by the patient model, the active substance supply rate to the anesthetic controller is changed such that the present active substance concentration is controlled to obtain a target value. Thus, the patient model anticipates the reaction of the patient's body with respect to several doses of active substance that have been given to the patient over past periods of time. The patient model is operated on the basis of a "predicting algorithm" taking into consideration the former active substances supplied the patient. In this fashion, the patient model delivers, on the basis of the preceding active substance rates and supply periods, the information concerning the present active substance concentration in the patient's body.

A typical conventional patient model is called a "pharmacokinetic model," and one such pharmacokinetic model is described by James R. Jacobs in the enclosed publication entitled "Algorithm for Optimal Linear

Model-Based Control with Application to Pharmacokinetic Model-Driven Drug Delivery" reproduced from IEEE Transactions on Biomedical Engineering, IEEE, Inc., New York, U.S.A., Volume 37, No. 1, published January 1990 at pages 107 through 109. Several portions of the latter publication have been highlighted, particularly the last paragraph in the left column of page 107 which describes that a desired (set point) plasma drug concentration (C_{pd}) is defined and at frequent intervals the set point is compared with the current prediction of the plasma drug concentration (C_{pp}) which is computed by real-time simulation of a pharmacokinetic model of the drug being infused. Figures 2 and 3 provide respectively infusion rates and a "pump control algorithm for pharmacokinetic model-driven delivery of intravenous drugs." The Examiner should note that Figure 3 makes specific reference to the infusion rate algorithm illustrated in Figure 2. The specifics in the form of a block control diagram for achieving infusion through the utilization of a pump control algorithm is also fully illustrated in Figure 1. For further evidence of enablement, the Examiner is invited to consider reference sources [3], [9], [12] and [13] appearing under the caption "REFERENCES" at page 109 of this publication.

This publication clearly describes an infusion rate control algorithm for a linear pharmacokinetic model, particularly with respect to Figures 1 through 3, in existence and known to persons skilled in the art at least as early as January 1990. From the latter date forward, over a dozen-plus years, there is absolutely no doubt that model computing means for calculating a current value of the present active substances concentration in a patient's body on the basis of a patient model was and remains well known in the art and can be made/replicated in the absence of undue

experimentation, particularly considering the level of person skilled in this art (which will be commented upon immediately hereinafter).

Filed herewith is another publication entitled "A Model-Based Self-Adjusting Two-Phase Controller for Vecuronium-Induced Muscle Relaxation During Anesthesia" from IEE Transactions on Biomedical Engineering, IEEE Inc., New York, U.S.A. Volume 34, No. 8, published August 1987, pages 583-584 under the authorship of Roman R. Jaklitsch and Dwayne R. Westenskow. The "level of skill in the art" is reflected by the B.S. degrees in electrical engineering and physics, respectively, of the writers and the advanced degrees (masters and doctorates) of each.

Chapter II entitled "PATIENT CHARACTERISTICS" (page 583) refers to a two-compartment pharmacokinetic model with non-linear pharmaco dynamics. The latter chapter also explains how the pharmacokinetic transfer functions ($G_{pk}(Z)$) is derived and also explains the manner in which the pharmaco dynamic relationship between the drug concentration and the "twitch height" is obtained (page 584, highlighted in yellow). At page 588, Figure 3 discloses a regulator control with a self-adjusting PID controller forming the patient model. For an overall broad based understanding of and the performance provided by the specifics of the controller disclosed in this article, the Examiner's attention is directed to page 593 and the entirety of the topic entitled "DISCUSSION."

Returning to the rejections set forth at page 2, paragraph 3 of the outstanding Office Action, the latter publications provide by convincing evidence that the present specification teaches one skilled in the art the manner in which the claimed invention can be practiced without undue experimentation. These publications individually and collectively also prove

convincingly that applicant has indeed disclosed to one skilled in the art all necessary formulae and/or algorithms that would enable "model computing means." Such "formulae and/or algorithms" are clearly well known and have been well known to persons skilled in the art since 1990 forward and today remain well within the realm of a person skilled in the art.

In view of the foregoing, the withdrawal of the Section 112 rejection, the second paragraph thereof, is believed to be in order and is herewith respectfully requested.

In view of the foregoing, the formal allowance of this application at an early date is herewith respectfully requested.

Respectfully submitted,

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Attachments: Publications (2)